11/9/76

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
1735 Baltimore
Kansas City, Missouri 64108

IN THE MATTER OF:

Applied Biochemists, Inc.
Mequon, Wisconsin

DOCKET NO. I.F.&R. V-329-C

Marvin E. Jones
Administrative Law Judge

INITIAL DECISION

On March 22, 1976, Complainant, the U.S. Environmental Protection Agency, filed its Complaint and Notice of Opportunity for Hearing against the Respondent,Applied Biochemists, Inc., via certified mail, requesting imposition of a civil penalty totaling $3910.00 and alleging that Respondent had violated Section 12 of the Federal Insecticide, Fungicide and Rodenticide Act, as amended [7 U.S.C. 135a(a)(1), 135b, as continued in effect by Section 4(b) of the FEPCA of 1972, and 7 U.S.C. 136j(a)(1)(E)], hereinafter FIFRA, in that a certain product, Black Algaetrine, a pesticide, was shipped by Respondent from its place of business, Mequon, Wisconsin, to Brewer Chemical Corporation, Honolulu, Hawaii. On this record, it is admitted that said shipment was made on or about January 13, 1975; that the product was not then registered under Section 4 of the FIFRA, as continued in effect under Section 4(a) of the FEPCA of 1972 in that registration for the product was thereafter granted and received by Respondent on April 17, 1975, and that the product was misbranded in that the label stated, in part, that it was registered under EPA Registration No. 8959-14AA, when in fact it was not so registered.

A Request for Hearing and Answer with Affirmative Defenses was filed by the Respondent on April 9, 1976. An Adjudicatory Hearing was scheduled and a prehearing conference was conducted by correspondence as provided by Section 168.36(d) and the parties complied with all requirements within the mandated time limits.

On September 1, 1976, Complainant moved for judgement on the pleadings which motion was taken under advisement for consideration at the time scheduled for hearing.

On September 30, 1976, the hearing was convened at the Federal Courthouse located in Milwaukee, Wisconsin, whereupon Complainant renewed its motion for and was granted judgement on the pleadings as regards liability and Respondent was allowed to proceed with the presentation of evidence bearing on the inappropriateness of and in mitigation of the proposed civil penalty. The parties having thereafter filed briefs, Proposed Findings of Fact and Conclusions of Law, and having fully considered the evidence and arguments of counsel, the undersigned makes and finds the following Findings of Fact and Conclusions of Law.

FINDINGS OF FACT

1. That the Respondent is a Wisconsin Corporation whose principal place of business is located at Mequon, Ozaukee County, Wisconsin, and is engaged in the manufacture and distribution of various water treatment products and chemicals, with annual gross sales, for the twelve months ending May 31, 1976, of approximately $900,000.

2. That APPLIED BIOCHEMISTS, INC. filed an application for registration with the Environmental Protection Agency in August of 1973, for the product known as Black Algaetrine.

3. That on February 22, 1974, Respondent forwarded its typewritten-corrected label to the Environmental Protection, together with all other necessary documentation for the registration for the product known as Black Algaetrine.

4. That on June 4, 1974, the Environmental Protection Agency forwarded a letter to APPLIED BIOCHEMISTS, INC. which stated as follows:

> "The product referred to above will be acceptable for registration under the Federal Insecticide, Fungicide and Rodenticide Act provided finished labeling is submitted.
>
> 'EPA Registration No. 8959-14' is being reserved for this product. This must appear on the finished label. The 'Notice of Registration' will be issued when five (5) copies of the accepted finished (printed) labeling are submitted. Finished labeling is that which will be attached to or accompany the product. Refer to the attached A-79 enclosure.
>
> To expedite handling, please return the enclosed duplicate copy of this letter with your finished labeling.
>
> This letter does not constitute registration, and the product may not be lawfully marketed in interstate commerce until it is registered.
>
> Sincerely,"

5. That in response thereto, Respondent caused approximately ten thousand (10,000) labels to be produced and on June 27, 1974, forwarded its finished labels to the Environmental Protection Agency.

6. That the cost of production of the labels and affixation of those labels to the containers used by APPLIED BIOCHEMISTS, INC, approximated $2,500 to $3,500.

7. That the verbiage used by APPLIED BIOCHEMISTS, INC. in its printed label submitted on June 27, 1974, was verbatim from the original typewritten-corrected label previously submitted to the Environmental Protection Agency on February 22, 1974.

8. That the EPA letter of June 4, 1974, raised no question with regard to the verbiage used by Respondent in its typewritte-corrected label previously submitted on February 22, 1974.

9. That on July 25, 1974, the Environmental Protection Agency forwarded a letter to APPLIED BIOCHEMISTS, INC. which stated as follows:

> "The labeling referred to above, submitted in connection with regiatration under the Federal Insecticide, Fungicide and Rodenticide Act, is not acceptable for the reasons given below. It should be corrected or amended in accordance with these comments and resubmitted in quintuplicate.
>
> Delete the phrase '...and in recommended pool dilutions is nontoxic to humans.' This safety claim would misbrand the product. Refer to Section 362.14(a)(5) of the Regulations for the enforcement of the Act. We regret this point was not made during our previous review.
>
> Revised, finished (printed) labels are required for registration.
>
> Sincerely,"

10. That in response thereto the Respondent, by letter dated August 5, 1974, forwarded the necessary corrected labels which deleted the questionable phrase and informed the Environmental Protection Agency as follows:

> "The phrase '...and in recommended pool dilutions is nontoxic to humans." will be deleted from our label as requested. This deletion will occur in our next printing and finished labels will be submitted <u>at that time</u>..(emphasis supplied)
>
> Thank you.
>
> Sincerely,"

11. That the Respondent had a history of dealing with the Environmental Protection Agency which allowed, in at least one instance, for subsequent amendment of labeling which would allow for the use of erroneous labels on hand with revisions to appear on subsequent printings.

12. That the Respondent received no communication from the Environmental Protection Agency after said letter of August 5, 1974, until March 24, 1975.

13. That the Respondent forwarded a letter dated December 6, 1974 to the Environmental Protection Agency which complied with its agreement to amend subsequent labels when the original consignment was expended. The content of that letter is as follows:

> "Enclosed you will find five (5) copies of our revised Black Algaetrine label with the required revision specified in your letter of July 5, 1974.
>
> These labels represent the text and graphics which will appear on the marketed container.
>
> Sincerely,"

14. That no response was received from the Environmental Protection Agency following submission of the revised labels on December 6, 1974, until March 24, 1975.

15. That between August 5, 1974, and March 24, 1975, Respondent shipped Black Algaetrine in interstate commerce in violation of the Act, using the said labels described above.

16. That the first communication from the Environmental Protection Agency to Respondent with regard to Black Algaetrine after July 25, 1974, was a telephone call on or about March 24, 1975, from the Agency to the Respondent at which time the Agency informed the Respondent that registration had not been issued.

17. That, in the preceding three year period, Respondent has experienced a decline in sales due to increased competition, and in the past year has had its line of credit of $250,000 withdrawn; and has received financial assistance in the sum of $36,000 from its President.

18. In 1976 Respondent's earnings decreased from 13 cents per share to 6 cents per share.

19. Respondent's building was purchased in 1975 for $132,000 and is mortgaged for $98,000.

20. That Respondent's violation was caused in part by the failure of the Environmental Protection Agency to process the application and/or to answer repeated inquiries and submissions by the Respondent.

21. That the Respondent's only prior history of noncompliance with the Act occurred in the fall of 1974 (Applied Biochemists, Inc., IF&R-V-208C, ID #115054, September 22, 1974).

22. That Respondent has taken the following steps to insure compliance with the Act.

(a) Hired additional personnel in an effort to prevent reoçcurrences of the same problem.

(b) Resorted to the internal procedure of using exclusively Certified Mail to insure response by the Environmental Protection Agency to inquiries.

(c) Has instituted a tickler system to insure compliance with the Act.

23. That there was no evidence of injury to any individual or to the environment as a result of the subject violation.

CONCLUSIONS OF LAW

1. The Respondent violated the Act in shipping the product known as Black Alagetrine in interstate commerce before receipt of registration.

2. The violation is attributable to the mistaken theory by Respondent that obtaining said registration was a "mere formality" aggravated by its attendant unconcern for duties placed on it by pertinent regulations; and to the unjustified inattention and delay on the part of Complainant.

DISCUSSION

In considering the issues of the instant case, it must be kept in focus that the applicable laws and regulations promulgated pursuant thereto are "regulatory" in nature, with the objective of controlling and directing the use, shipment, distribution, and sale of "pesticides" so that, where present, the danger of undesirable side effects on human health and the environment can either be avoided or completely alleviated.

Registration and labeling are two of the regulatory tools which can be utilized effectively to avert such dangers and, in instances where a safe use cannot be realized, to cancel registration of undesirable products. It is clear that it is at the time of registration that human health and environmental problems of pesticides, if any, should be discerned.

Failure to apply appropriate sanctions where the Act is violated will, in effect, invite violations in increasing numbers which could ultimately frustrate and defeat the scheme of regulation contemplated by the Act.

The violation with which Respondent is here charged does not, standing alone, appear to have brought about grave consequences to humanity or the environment; but, on principle, it can be seen that the effect of this violation, in conjunction with the effect of many

others, is far from trivial. (cf Wickard v Filburn, 317 US 111, 635 ct. 82). For this reason, adherence to and application of the letter of the statute and the applicable regulations is essential to an equitable consideration of the facts and the circumstances with which we are here presented. While the factors enumerated in Section 168.60(b)(1) can be considered in mitigation (as well as in aggravation) of the civil penalty to be assessed, any single factor should not be considered as a defense per se.

CIVIL PENALTY

In determining the amount of penalty to be assessed, Section 14(a)(3) of the statute [7 U.S.C. 136l(a)(3)] requires that there shall be considered the appropriateness of the penalty to the size of respondent's business, the effect on respondent's ability to continue in business and the gravity of the violation. Section 168.60(b) of the rules of practice provides that in evaluating the gravity of violation there shall also be considered respondent's history of compliance with the Act and any evidence of good faith or lack thereof.

Respondent is a relatively large company and though its financial picture has been clouded by financial reversals of varying extent I do not find that assessment of a penalty, even in the amount proposed, will adversely affect its ability to continue in business.

I have considered evidence bearing on the gravity of the violation from the standpoints of gravity of harm and gravity of misconduct. I find some basis in this record for finding adverse to Respondent from the gravity of harm aspect, considering the character of the product sold and from the changes required and which are now utilized; however, this aspect is greatly mitigated under the facts and circumstances which indicate an absence of concern on the part of

Complainant, at least until after the date of violation. There was misconduct on the part of Respondent in shipping said product in interstate commerce without having formally obtained the required registration. However, as hereinbefore indicated, the Complainant, by its failures and omissions contributed to some extent to the creation of the violation here complained of. Respondent once before failed to fully comply with the regulations. In that instance, as here, I do not discern that there existed an intent to violate the law. In this regard it is worthy of mention that intent is not an element of the offense charged under the civil penalty provision of FIFRA as amended[1/]. [cf United States v Dotterweich, 320 U.S. 277 (1943)]. Further, I do not find that Respondent's violation is attributable to its failure to act in good faith.

Section 168.46(b) of the Rules of Practice provides that "the Administrative Law Judge may at his discretion increase or decrease the assessed penalty from the amount proposed to be assessed in the Complaint."

I have considered the nature and gravity of the violation. I have further considered the effect of the inattention and delays attributable to Complainant in its handling of Respondent's application and correspondence concerning same. Even though Respondent is a relatively large company and able to pay the penalty proposed, its financial well-being has been clouded to some extent by recent financial reverses. Accordingly, I am of the view that a penalty of $1150.00 is appropriate.

1/ The Criminal Penalty section of the Act, 14(b), requires that the violation be "knowingly".

Having considered the entire record and based on the Findings of Fact and Conclusions herein, it is proposed that the following Order be issued:

"FINAL ORDER[2/]

Pursuant to Section 14(a)(1) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended [7 U.S.C. 136l(a)(1)], a civil penalty of $1150.00 is assessed against Respondent Applied Biochemists, Inc., Mequon, Ozaukee County, Wisconsin, for violations of said Act which have been established on the basis of Complaint issued on March 22, 1976, and Respondent is ordered to pay the same by Cashier's or Certified Check, payable to the United States Treasury, within sixty (60) days of the receipt of this order."

This Initial Decision is signed and filed this 9th day of November 1976, at Kansas City, Missouri.

Marvin E. Jones
ALJ

2/ The Initial Decision and the proposed Final Order assessing a civil penalty shall become the Final Order of the Regional Administrator, unless appealed or reviewed by the Regional Administrator as provided in 40 CFR 168.46(c).